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10/524,195	02/10/2005	Ryoji Fujii	10873.1633USWO	4102

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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.  
P.O. BOX 2902-0902  
MINNEAPOLIS, MN 55402

EXAMINER
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GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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05/07/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/524,195	Applicant(s) FUJII, RYOJI	
	Examiner Andrew M. Gilbert	Art Unit 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Acknowledgements***

1. This office action is in response to the reply filed on 2/22/2007.
2. In the reply the Applicant argued the rejection. Thus, claims 1-19 are pending for examination.
3. Additionally, in the reply, the Applicant submitted a replacement drawing sheet for Fig 8a to obviate the objections to the drawings and explicitly clarified an inner-end place that has an oval shape whose major axis is in the same direction as the breadth direction of the main body to obviate the 112(2<sup>nd</sup>) paragraph rejections

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 7, 10, 13, 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Willis et al (6767340). In reference to claim 1, Willis et al discloses a needleless port (Fig 1-2) comprising: a pedestal that forms a part of a flow channel (14) and has an opening to the flow channel; a cover (12, 40) that is engaged with the pedestal at a position corresponding to the opening and has a cavity that opens to exterior (Fig 1-3) at a predetermined distance from the opening; and a septum that is held in the cavity (42) and is made of a resilient material with a passageway for allowing an insertion member to be inserted from the exterior to the opening (Fig 7), wherein the

septum comprises a main body (Fig 3, 8) that extends from an inner end on the pedestal side toward an outer end on the exterior side of the cavity of the cover, with the passageway being formed between an inner-end face and an outer-end face thereof and compression ribs (80) provided on an external surface of the main body the main body has a cross section in a direction orthogonal to the passageway of a shape having an external dimension in a length direction larger than that in a breadth direction (42, Fig 8); the passageway includes a slit (74) and a bore (52, Fig 3, 7-8), the slit having a predetermined depth from the outer-end face of the main body and extending in the same direction as the length direction, and the bore extending from the slit to the inner-end face of the main body and having a lateral section of a spindle shape whose major axis extends in the same direction as the length direction (Fig 3, 7-8); additionally, compression ribs can be provided at the both side ends of the main body in the breadth direction (80, Fig 8) so as to extend along the axial direction of the passageway, the cavity of the cover has a circular cross section whose diameter is smaller than a distance between the external surfaces of the compression ribs (Figs 3, 7-8; col 4, lns 25-35), and with the septum being held inside the cavity a space is formed between an external surface of the main body at a part without the compression ribs and an internal wall of the cover, and the bore is dosed by a compressive force applied from the internal wall of the cover to the septum via the compression ribs (col 4, lns 25-35; Fig 3, 7-8).

6. In reference to claim 2, Willis et al discloses the invention substantially as claimed in regards to claim 1, and additionally discloses a substantial passageway (52), the substantial passageway includes an unpenetrated region (74) and a bore (52; Figs

3, 7-8), and the compression ribs (80) are provided at the both side ends of the main body in the length direction so as to extend along the axial direction of the substantial passageway (Figs 8).

7. In reference to claim 3, Willis et al discloses the septum having an inner end plate that has an oval shape whose major axis extends in the same direction as the length direction of the main body (68, Fig 8).

8. In reference to claim 4, Willis et al discloses the invention substantially as claimed and additionally discloses the septum having, around an outer end of the main body, an outer-end plate that is exposed to outside of the cover and is larger in size than an inside diameter of the cover at an outer end of the cover (Figs 3, 8; col 4, lns 25-35).

9. In reference to claim 5, Willis et al discloses wherein the lengths of the major axis and the minor axis of the section of the bore gradually become larger from the outer end face of the main body toward the inner-end face of the main body (Figs 3, 7, 8).

10. In reference to claim 7, Willis et al discloses the invention substantially as claimed and additionally discloses a surface of the outer-end plate is flat (74, 80; Figs 8).

11. In reference to claim 10, Willis et al discloses wherein the internal wall of the cover forming the cavity is tapered so that the diameter of the cavity section gradually becomes smaller from the inner end thereof toward the outer end thereof along an axis of the cavity (Figs 3, 7, 8; 56)

12. In reference to claim 13, Willis et al discloses an area size of a cross section of the space between the external surface of the main body at the portion without the compression ribs and the internal wall of the cover from an outer end toward an inner end of the cover (Figs 3, 7, 8; 70, 72, 56)

13. In reference to claim 16, Willis et al discloses an annular rib (68) is provided around the opening of the pedestal, the annular rib projecting toward the cover, and the inner end plate of the septum is sandwiched between the internal wall of the cover and the annular rib so that the annular rib engages with a bottom surface of the inner-end plate, thereby establishing liquid tightness (Fig 7, 66, 62, 60, 68).

14. In reference to claim 17, Willis et al discloses the internal wall of the cover has one or more indents that are engaged with an external surface of the septum (Figs 3, 7, 8; 56).

15. In reference to claim 18, Willis et al discloses the invention substantially as claimed and additionally discloses an inner peripheral portion at an outer end of the cover is chamfered (Figs 3, 7, 8; 56).

16. In reference to claim 19, Willis et al discloses the invention substantially as claimed and additionally discloses wherein the material of the septum is a silicone rubber (col 4, lns 50-57).

### ***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willis et al. Willis et al discloses the invention substantially as claimed except for expressly disclose the septum having, on an outer end thereof, a surface depression portion which is formed at a central area to be substantially level and depressed in relation to an area surrounding the central area. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the septum having, on an outer end thereof, a surface depression portion which is formed at a central area to be substantially level and depressed in relation to an area surrounding the central area because the Applicant has not disclosed that having the septum having, on an outer end thereof, a surface depression portion which is formed at a central area to be substantially level and depressed in relation to an area surrounding the central area provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the septum surface of Willis et al because the septum surface performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify Willis et al to obtain the invention as specified in claim 6.

19. Claims 8-9, 11-12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willis et al. Willis et al discloses the invention substantially as claimed except for expressly disclosing a length  $L_{SO}$  of the main body in a state in which the septum is not mounted inside the cover is smaller than a length  $L_c$  of the

cover at a portion for holding the main body therein; wherein the septum being held inside the cover, an expansion ration is within a range of 5% to 40%, the expansion ration being calculated by dividing an expanded length of the septum by the length  $L_c$ ; a ratio of the distance between the external surfaces of the compression ribs to the inside diameter of the cover and a ratio of the length in the major axis of the inner-end plate to the inside diameter of the cover are each within a range of 1.05 to 1.4; a ratio of a dimension in the breadth direction of the main body to the inside diameter of the cover and a ration of a minor axis of the inner-end plate to the inside diameter of the cover are each within a range of 0.8 to 1.0; a ratio of the predetermined depth of the slit to a height of the main body of the septum is within a range of 0.04 to 0.60, the predetermined depth being measured in a direction of the passageway; the predetermined depth of the slit measured in a direction of the passageway is within a range of 0.2 mm to 3.0 mm.

20. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have these recited limitations of claims 8-9, 11-12, 14-15 because the Applicant has not disclosed that the recited limitations of claims 8-9, 11-12, 14-15 provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with needless port of Atkinson because the needless port of Willis et al performs substantially the same function as the claimed invention of the Applicant. Therefore, it would have been an



obvious matter of design choice to modify Willis et al to obtain the invention as specified in claims 8-9, 11-12, 14-15.

***Response to Arguments***

21. Applicant's arguments filed 2/22/2007 have been fully considered but they are not persuasive.

22. The Applicant argues that:

- i. Willis et al fails to disclose a slit having a predetermined depth from an outer-end face of a main body and a bore extending from the slit to an inner-end face of the main body (Remarks, pg 5, paragraph 1)
- ii. Willis et al fails to disclose the bore being closed by a compressive force applied from an internal wall of the cover to the septum via compression ribs (Remarks, pg 5, paragraph 2).

23. In response to the applicant's argument (i), the Examiner notes that the Applicant has not defined that the slit originates in an outer-end face and extends a predetermined depth towards the inner-end face. Rather, the Applicant has merely defined the slit as having a predetermined depth *from* an outer-end face. The slit (74) of Willis et al has a predetermined depth that extends away from the outer-end face (68). The Examiner strongly suggests amending the claim limitations to recite that the slit originates in or at an outer-end face and extends a predetermined depth towards the inner-end face to further clarify the Applicant's invention and overcome the prior art of record.

24. Additionally, in response to the applicant's argument (i), the Examiner notes that the Examiner has interpreted "a bore extending from the slit to an inner-end face of the main body" to be present in Willis et al. Namely, Willis et al discloses a bore (52, Fig 3) originating at the outer end face (68) and traveling towards a slit (74) at the inner end face (shown by reference number 80 in Fig 3). When the insertion member is inserted into the bore (Fig 7) pushing against the compression ribs and opens the slit (Fig 7) whereby the bore is now inclusive of the opening formed in the slit and the bore extends from the slit to an inner-end face of the main body. The Examiner suggests further clarifying the Applicant's invention by adding the claim limitation that the bore extends from the slit to an inner-end face of the main body prior to insertion of an insertion member to overcome the prior art of record.

25. In response to the applicant's argument (ii), the Examiner notes that as discussed in the paragraph above the bore (52) is being closed by a compressive force applied from an internal wall of the cover (Fig 3) to the septum via compression ribs (80, Fig 3, 8). This causes the septum's bore being closed shut at the sit of the slit as shown in Fig (3). When an insertion member is inserted into the bore, the insertion member contacts the sidewalls of the septum and forcibly pushed against the compression ribs, overcoming the compression force and causing the slit to open as shown in Fig (7).

### ***Conclusion***

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lynn et al (5178607), McPhee (5199948).

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER  
